

**elf atochem**

ELF ATOCHEM NORTH AMERICA, INC.

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Tel: 215-337-6500

Contains No CBI

October 12, 1992

**CERTIFIED MAIL**

**RETURN RECEIPT REQUESTED**

Document Processing Center (TS-790)  
Office of Toxic Substances  
U.S. Environmental Protection Agency  
401 M St., S.W.  
Washington, D.C. 20460

Attn: Section 8(e) Coordinator (CAP Agreement)

RE: Report Submitted Pursuant to the TSCA Section 8(e)  
Compliance Audit Program

CAP Identification Number: 8ECAP-0026

Dear Sir/Madam:

Pursuant to the Toxic Substances Control Act (TSCA) Section 8(e) Compliance Audit Program and the Agreement for TSCA Section 8(e) Compliance Audit Program (CAP Agreement) executed by Elf Atochem North America Inc. (Atochem) and Environmental Protection Agency (EPA), Atochem is submitting the enclosed eye irritation studies to the EPA. Eye irritation studies were conducted both with and without eye washout. These studies do not involve effects in humans.

Nothing in this letter or the enclosed studies is considered confidential business information of Atochem.

The enclosed studies provide information on the chemical trioctylphosphine oxide which has CAS number 78-50-2.

The title of the enclosed studies are Draize Eye Irritation Study in Albino Rabbits With Trioctylphosphine Oxide and Draize Eye Irritation Study in Albino Rabbits Using Trioctylphosphine Oxide With Washout. The following is a summary of the adverse effects observed in these studies.

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2/9/95

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TSCA CAP  
Trioctylphosphine Oxide  
October 12, 1992  
Page Two

Application of one-tenth (0.1) gram of trioctylphosphine oxide to the right eye of each of six New Zealand albino rabbits resulted in extreme irritation and corneal opacity in all test animals. Flushing the eyes with 20 ml of water every 3 minutes for 15 minutes after a 5 minute application of the test material to the right eye of an additional six rabbits reduced the degree of irritation.

To our knowledge, Atochem has not previously submitted any TSCA Section 8(e) notices or premanufacture notifications on the subject chemical.

Further questions regarding this submission may be directed to me at 215 337-6892.

Sincerely,



C.H. Farr, PhD, DABT  
Manager, Product Safety  
and Toxicology

Enclosures

FILED IN 54 28-25

TR 91-838



PRINCETON PIKE, P. O. BOX 57

PRINCETON, N. J. 08540

TEL.: (509) 924-9658

Project #20-178

M-402

Draize Eye Irritation Study in Albino Rabbits  
with Trioctylphosphine Oxide

Conducted for

M & T Chemicals, Inc.  
Rahway, New Jersey

Submitted by

AME Associates  
Princeton, New Jersey

CAS: 78-50-2

A. M. E. ASSOCIATES P.O. BOX 57 PRINCETON, N. J. 08540

November 28, 1966

PROJECT #20-178

SPONSOR: M & T CHEMICALS, INC.

SUBJECT: Draize Eye Irritation Study in Albino Rabbits with  
Trioctylphosphine Oxide

OBJECTIVE

To conduct a rabbit eye irritation study with  
Trioctylphosphine Oxide.

MATERIAL

Trioctylphosphine Oxide supplied by M & T Chemicals,  
Inc., for use in this study.

PROCEDURE

A group of six (three males and three females) normal, healthy albino rabbits of the New Zealand White Strain was employed in this study. The right eye of each animal was held open so that the palpebral and bulbar conjunctivae were exposed and 0.1 g of the experimental material was placed in the eye. The left eye, untreated, served as a control.

Evaluations of the eyes of the rabbits were performed at 24, 48 and 72 hours after instillation of the test material. Three or four drops of 2% fluorescein were instilled into each eye once during the experimental period. A u-v lamp was utilized to aid in reading the eyes.

-2-

The scoring method employed was that described by Draize on page 51 of "Appraisal of the Safety of Chemicals in Foods, Drugs, and Cosmetics" published by the Association of Food and Drug Officials of the United States.

Draize Scale for Scoring Ocular Lesions

I Cornea

A. Opacity - Degree of Density (area which is most dense taken for reading)

Scattered or diffuse area - details of iris clearly visible.....	1
Easily discernible translucent areas, details of iris slightly obscured.....	2
Opalescent areas, no details of iris visible, size of pupil barely discernible.....	3
Opaque, iris invisible.....	4

B. Area of Corneal Damage Involved

One-quarter of area (or less) but not zero.....	1
Greater than one-quarter, less than one-half.....	2
Greater than one-half, less than three-quarters.....	3
Greater than three-quarters, up to whole area.....	4

Score equals A x B x 5

Total Maximum 80

II Iris

A. Folds above normal, congestion swelling, circum-  
corneal injection (any one or all of these or

-3-

combination of any thereof) iris still reacting to light (sluggish reaction is positive).....	1
No reaction to light, hemorrhage, gross destruction (any one or all of these).....	2
Score equals A x 5	Total Maximum 10

### III Conjunctivae

A. Redness (refers to palpebral and bulbar conjunctivae  
excluding cornea and iris)

Vessels definitely injected above normal.....	1
More diffuse, deeper crimson red, individual vessels not clearly discernible.....	2
Diffuse beefy red.....	3

B. Chemosis

Any swelling above normal.....	1
Obvious swelling with partial eversion of the lids...	2
Swelling with lids about half closed.....	3
Swelling with lids about half to completely closed...	4

C. Discharge

Any amount different from normal (does not include small amount observed in inner canthus of normal animals).....	1
Discharge with moistening of the lids and hairs just adjacent to the lids.....	2

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Discharge with moistening of the lids and considerable	
area around eye.....	3
Score (A + B + C) x 2	Total Maximum 20

The maximum total score is the sum of all scores obtained for the cornea, iris, and conjunctivae.

Total maximum score possible - 110 points.

## RESULTS

Table 1 shows the individual readings for the cornea, iris and conjunctivae after 24, 48 and 72 hours. An average score per group per day is also reported. Severe reactions were noted at the 24, 48 and 72 hour observation periods, with slight improvement noted at both the 48 and 72 hour readings.

## CONCLUSION

Utilizing the Draize method for the rabbit eye irritation test, it can be concluded that M & T Chemicals, Inc., Trioctylphosphine Oxide is a severe irritant to the rabbit eye.

SUBMITTED BY

AME ASSOCIATES

Russell S. Edmonds, V.M.D.

President

TABLE 1  
 Trioctylphosphine Oxide  
 Rabbit Eye Irritation Study

<u>Time Hours</u>	<u>Rabbit Number</u>						<u>Average Score Per Group</u>
	<u>1</u>	<u>2</u>	<u>3</u>	<u>4</u>	<u>5</u>	<u>6</u>	
24	I. Cornea						
	A. Opacity	4	4	4	4	4	
	B. Area Involved	4	4	4	4	4	
	II. Iris						
	A. Evaluation	2	2	2	2	2	110.0
	III. Conjunctivae						
	A. Hyperemia	3	3	3	3	3	
	B. Chemosis	4	4	4	4	4	
	C. Discharge	3	3	3	3	3	
	Total Max. Score	110	110	110	110	110	
	I. Cornea						
	A. Opacity	4	4	4	4	4	
48	B. Area Involved	3	3	3	3	3	
	II. Iris						
	A. Evaluation	2	2	2	2	2	86.0
	III. Conjunctivae						
	A. Hyperemia	2	3	3	2	2	
	B. Chemosis	3	3	3	3	3	
	C. Discharge	2	2	3	2	3	
	Total Max. Score	84	86	88	84	86	
	I. Cornea						
	A. Opacity	3	3	4	3	4	
	B. Area Involved	3	3	3	3	3	
72	II. Iris						
	A. Evaluation	2	2	2	2	2	76.5
	III. Conjunctivae						
	A. Hyperemia	2	2	3	2	2	
	B. Chemosis	2	3	2	2	3	
	C. Discharge	2	2	3	2	2	
	Total Max. Score	67	69	86	67	84	





PRINCETON PIKE, P. O. BOX 57

PRINCETON, N. J. 08540

TEL.: (609) 924-9658

Project #20-178

M-403

Draize Eye Irritation Study in Albino Rabbits  
Using Trioctylphosphine Oxide with Washout

Conducted for

M & T Chemicals, Inc.  
Rahway, New Jersey

Submitted by

AME Associates  
Princeton, New Jersey

CAS: 78-50-2

A. M. E. ASSOCIATES P.O. BOX 57 PRINCETON, N. J. 08540 .

December 5, 1966

PROJECT #20-173

SPONSOR: M & T CHEMICALS, INC.

SUBJECT: Draize Eye Irritation Study in Albino Rabbits  
Using Trioctylphosphine Oxide with Washout

OBJECTIVE

To conduct a rabbit eye irritation study with  
Trioctylphosphine Oxide.

MATERIAL

Trioctylphosphine Oxide supplied by M & T Chemicals,  
Inc., for use in this study.

PROCEDURE

A group of six normal healthy albino rabbits (three males and three females) was employed in this study. The right eye of each animal was held open so that the palpebral and bulbar conjunctivae were exposed and 0.1 g of the experimental material was placed in the eye. The left eye, untreated, served as a control. After a 5 minute contact period, these rabbits had their treated eyes washed every 3 minutes for 15 minutes using 20 ml of warm water each time.

Evaluations of the treated eyes were performed at 24, 48 and 72 hours after instillation of the test material.

-2-

Three or four drops of 2% fluorescein were instilled into each treated eye once during the experimental period. A u-v lamp was used to aid in reading the eyes.

The scoring method employed was that described by Draize on page 51 of "Appraisal of the Safety of Chemicals in Foods, Drugs and Cosmetics" published by the Association of Food and Drug Officials of the United States.

Draize Scale for Scoring Ocular Lesions

I Cornea

A. Opacity - Degree of Density (area which is most dense taken for reading)

Scattered or diffuse area, details of iris clearly visible.....	1
Easily discernible translucent areas, details of iris slightly obscured.....	2
Opalescent areas, no details of iris visible, size of pupil barely discernible.....	3
Opaque, iris invisible.....	4

B. Area of Corneal Damage Involved

One-quarter of area (or less) but not zero.....	1
Greater than one-quarter, less than one-half.....	2
Greater than one-half, less than three quarters.....	3
Greater than three-quarters, up to whole area.....	4

Score equals A x B x 5

Total Maximum 80

-3-

## II Iris

A. Folds above normal, congestion, swelling, circum-	
corneal injection (any one or all of these or	
combination of any thereof) iris still reacting	
to light (sluggish reaction is positive).....	1
No reaction to light, hemorrhage, gross destruction	
(any one or all of these).....	2
Score equals A x 5	Total Maximum 10

## III Conjunctivae

A. <u>Redness</u> (refers to palpebral and bulbar conjunctivae	
excluding cornea and iris)	
Vessels definitely injected above normal.....	1
More diffuse, deeper crimson red, individual vessels	
not clearly discernible.....	2
Diffuse beefy red.....	3
B. <u>Chemosis</u>	
Any swelling above normal.....	1
Obvious swelling with partial eversion of the lids...	2
Swelling with lids about half closed.....	3
Swelling with lids about half to completely closed...	4
C. <u>Discharge</u>	
Any amount different from normal (does not include	
small amount observed in inner canthus of normal	
animals).....	1

-4-

Discharge with moistening of the lids and hairs just adjacent to the lids.....	2
Discharge with moistening of the lids and considerable area around eye.....	3
Score (A + B + C) x 2	Total Maximum 20

The maximum total score is the sum of all scores obtained for the cornea, iris and conjunctivae.

Total maximum score possible - 110 points.

#### RESULTS

Table 1 lists the individual scoring for the cornea, iris and conjunctivae for each rabbit after 24, 48 and 72 hours. An average score per group per day is also reported. All rabbits showed severe irritation at the 24 hour scoring period. At the 48 and 72 hour observation considerable improvement was seen.

#### CONCLUSION

Utilizing the Draize scoring method for the rabbit eye irritation test, it can be concluded that M & T Chemicals, Inc., Trioctylphosphine Oxide is moderately irritating to the rabbit eye after an exposure period of 5 minutes followed by washing.

SUBMITTED BY

Russell S. Edmonds  
AME ASSOCIATES

Russell S. Edmonds, V.M.D.  
President

TABLE 1

## Trioctylphosphine Oxide

## Rabbit Eye Irritation Study with Washout

<u>Time</u> <u>Hours</u>		<u>Rabbit Number</u>						<u>Average Score</u> <u>Per Group</u>
		<u>1</u>	<u>2</u>	<u>3</u>	<u>4</u>	<u>5</u>	<u>6</u>	
24	I. Cornea							
	A. Opacity	3	4	3	3	3	3	
	B. Area Involved	4	4	4	4	4	4	
	II. Iris							
	A. Evaluation	2	2	2	2	2	2	91.0
	III. Conjunctivae							
	A. Hyperemia	3	2	3	3	3	3	
	B. Chemosis	3	3	3	3	3	3	
	C. Discharge	3	3	3	3	3	3	
	Total Max. Score	88	106	88	88	88	88	
48	I. Cornea							
	A. Opacity	3	3	3	3	3	3	
	B. Area Involved	3	3	3	3	3	3	
	II. Iris							
	A. Evaluation	2	1	2	2	2	2	67.8
	III. Conjunctivae							
	A. Hyperemia	2	2	2	2	2	3	
	B. Chemosis	2	2	2	2	2	2	
	C. Discharge	2	3	2	3	3	3	
	Total Max. Score	67	64	67	69	69	71	
72	I. Cornea							
	A. Opacity	1	2	2	1	2	1	
	B. Area Involved	2	2	2	2	2	2	
	II. Iris							
	A. Evaluation	1	1	1	2	1	2	29.0
	III. Conjunctivae							
	A. Hyperemia	1	1	1	1	1	1	
	B. Chemosis	1	2	2	1	2	1	
	C. Discharge	2	2	2	2	2	2	
	Total Max. Score	23	35	35	23	35	23	



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

C. H. Farr, PhD, DABT  
Manager, Product Safety and Toxicology  
Atochem North America, Inc.  
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P.O. Box 1536  
King of Prussia, Pennsylvania 19406-0018

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

APR 18 1995

EPA acknowledges the receipt of information submitted by your organization under Section 8(e) of the Toxic Substances Control Act (TSCA). For your reference, copies of the first page(s) of your submission(s) are enclosed and display the TSCA §8(e) Document Control Number (e.g., 8EHQ-00-0000) assigned by EPA to your submission(s). Please cite the assigned 8(e) number when submitting follow-up or supplemental information and refer to the reverse side of this page for "EPA Information Requests".

All TSCA 8(e) submissions are placed in the public files unless confidentiality is claimed according to the procedures outlined in Part X of EPA's TSCA §8(e) policy statement (43 FR 11110, March 16, 1978). Confidential submissions received pursuant to the TSCA §8(e) Compliance Audit Program (CAP), should already contain information supporting confidentiality claims. This information is required and should be submitted if not done so previously. To substantiate claims, submit responses to the questions in the enclosure "Support Information for Confidentiality Claims". This same enclosure is used to support confidentiality claims for non-CAP submissions.

Please address any further correspondence with the Agency related to this TSCA 8(e) submission to:

Document Processing Center (7407)  
Attn: TSCA Section 8(e) Coordinator  
Office of Pollution Prevention and Toxics  
U.S. Environmental Protection Agency  
Washington, D.C. 20460-0001

EPA looks forward to continued cooperation with your organization in its ongoing efforts to evaluate and manage potential risks posed by chemicals to health and the environment.

Sincerely,

*Terry R. O'Bryan*

Terry R. O'Bryan  
Risk Analysis Branch

Enclosure

12670A



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### Triage of 8(e) Submissions

Date sent to triage: APR 20 1995

NON-CAP

CAP

Submission number: 12670A

TSCA Inventory:

Y

N

D

Study type (circle appropriate):

Group 1 - Dick Clements (1 copy total)

ECO

AQUATO

Group 2 - Ernie Falke (1 copy total)

ATOX

SBTOX

SEN

w/NEUR

Group 3 - Elizabeth Margosches (1 copy each)

STOX

CTOX

EPI

RTOX

GTOX

STOX/ONCO

CTOX/ONCO

IMMUNO

CYTO

NEUR

Other (FATE, EXPO, MET, etc.): \_\_\_\_\_

Notes:

**THIS IS THE ORIGINAL 8(e) SUBMISSION; PLEASE REFILE AFTER TRIAGE DATABASE ENTRY**

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entire document 0 1 2 pages 1/2

pages 1/2, 1/2, 1/2

Notes:

Contractor reviewer : POL

Date:

3/29/95



CECATS/TRIAGE TRACKING DBASE ENTRY FORM

CECATS DATA: Submission # 8EHQ 1092-12670 SEQ. A

TYPE: (INT) SUPP FLWP

SUBMITTER NAME: Elf Atoc sm North

America, Inc.

INFORMATION REQUESTED: FLWP DATE: \_\_\_\_\_

0501 NO INFO REQUESTED

0502 INFO REQUESTED (TECH)

0503 INFO REQUESTED (VOL ACTIONS)

0504 INFO REQUESTED (REPORTING RATIONALE)

DISPOSITION:

0502 REFER TO CHEMICAL SCREENING

0503 CAP NOTICE

0501 NO ACTION REPORTED

0502 STUDIES PLANNED/IN PROGRESS

0503 NOTIFICATION OF WORK REQUIRED

0504 LABEL/MSDS CHANGES

0505 PROCESS/HANDLING CHANGES

0506 APP/USE DISCONTINUED

0507 PRODUCTION DISCONTINUED

0508 CONFIDENTIAL

SUB. DATE: 10/12/92 OTS DATE: 10/26/92 CSRAD DATE: 02/09/95

CHEMICAL NAME: \_\_\_\_\_

CASE# 78-50-2

INFORMATION TYPE:	P F C	INFORMATION TYPE:	P F C	INFORMATION TYPE:	P F C
0201 ONCO (HUMAN)	01 02 04	0216 EPICLIN	01 02 04	0241 IMMUNO (ANIMAL)	01 02 04
0202 ONCO (ANIMAL)	01 02 04	0217 HUMAN EXPOS (PROD CONTAM)	01 02 04	0242 IMMUNO (HUMAN)	01 02 04
0203 CELL TRANS (IN VITRO)	01 02 04	0218 HUMAN EXPOS (ACCIDENTAL)	01 02 04	0243 CHEM/PHYS PROP	01 02 04
0204 MUTA (IN VITRO)	01 02 04	0219 HUMAN EXPOS (MONITORING)	01 02 04	0244 CLASTO (IN VITRO)	01 02 04
0205 MUTA (IN VIVO)	01 02 04	0220 ECO/AQUA TOX	01 02 04	0245 CLASTO (ANIMAL)	01 02 04
0206 REPRO/TERATO (HUMAN)	01 02 04	0221 ENV. OCCUREL/FATE	01 02 04	0246 CLASTO (HUMAN)	01 02 04
0207 REPRO/TERATO (ANIMAL)	01 02 04	0222 EMER INCI OF ENV CONTAM	01 02 04	0247 DNA DAM/REPAIR	01 02 04
0208 NEURO (HUMAN)	01 02 04	0223 RESPONSE REQUEST DELAY	01 02 04	0248 PROD/USE/PROC	01 02 04
0209 NEURO (ANIMAL)	01 02 04	0224 PROD/COMP/CHEM ID	01 02 04	0251 MSDS	01 02 04
0210 ACUTE TOX. (HUMAN)	01 02 04	0225 REPORTING RATIONALE	01 02 04	0299 OTHER	01 02 04
0211 CHR. TOX. (HUMAN)	01 02 04	0226 CONFIDENTIAL	01 02 04		
0212 ACUTE TOX. (ANIMAL)	01 02 04	0227 ALLERG (HUMAN)	01 02 04		
0213 SUB ACUTE TOX (ANIMAL)	01 02 04	0228 ALLERG (ANIMAL)	01 02 04		
0214 SUB CHRONIC TOX (ANIMAL)	01 02 04	0229 METAB/PHARMACO (ANIMAL)	01 02 04		
0215 CHRONIC TOX (ANIMAL)	01 02 04	0230 METAB/PHARMACO (HUMAN)	01 02 04		

USE: \_\_\_\_\_ PRODUCTION: \_\_\_\_\_

SPECIES PGT TOXICOLOGICAL CONCERN: \_\_\_\_\_

ONGOING REVIEW

TRIAGE DATA NON-CBI INVENTORY

YES (DROP/REFER)

YES

NO

NO (CONTINUE)

REFR

IN TERMINI

CAS SR

CONFID

8(E) -12670A

H

ACUTE EYE IRRITATION IN NEW ZEALAND WHITE RABBITS IS OF HIGH CONCERN BASED ON EXTREME IRRITATION AND CORNEAL OPACITY (3/3 M, 3/3 F) AT THE FINAL TIME OF OBSERVATION (72 HOURS) FROM EXPOSURE TO 0.1 G.